

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

NATIONAL INFUSION CENTER
ASSOCIATION *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity
as Secretary of the Department of Health and
Human Services, *et al.*,

Defendants.

Case No. 1:23-cv-00707-DAE

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO DISMISS

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TABLE OF CONTENTS

INTRODUCTION.....	1
ARGUMENT.....	1
I. Plaintiff NICA should be dismissed for lack of subject-matter jurisdiction	1
A. NICA has not satisfied the jurisdictional prerequisites of the Medicare Act	1
B. NICA has not identified any member with Article III standing	5
II. Upon NICA's dismissal, this case should be dismissed for lack of venue	10
CONCLUSION.....	10

TABLE OF AUTHORITIES

CASES

<i>Affiliated Prof'l Home Health Care Agency v. Shalala,</i> 164 F.3d 282 (5th Cir. 1999)	4
<i>Am. C.R. Union v. Martinez-Rivera,</i> 166 F. Supp. 3d 779 (W.D. Tex. 2015)	6
<i>Am. Med. Hospice Care, LLC v. Azar,</i> No. 5:20-cv-757-DAE, 2020 WL 9814144 (W.D. Tex. Dec. 9, 2020)	2, 4
<i>Association of Community Cancer Centers v. Azar,</i> 509 F. Supp. 3d 482 (D. Md. 2020)	4
<i>Attala Cnty., Miss. Branch of NAACP v. Evans,</i> 37 F.4th 1038 (5th Cir. 2022)	7, 9
<i>Axon Enterprises, Inc. v. FTC,</i> 598 U.S. 175 (2023)	10
<i>Clapper v. Amnesty Int'l USA,</i> 568 U.S. 398 (2013)	7, 8, 9
<i>Community Oncology Alliance, Inc. v. OMB,</i> 987 F.3d 1137 (D.C. Cir. 2021)	4
<i>D&G Holdings, LLC v. Becerra,</i> 22 F.4th 470 (5th Cir. 2022)	3
<i>Dayton Area Chamber of Com. v. Becerra,</i> No. 3:23-cv-156, — F. Supp. 3d —, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023)	1
<i>Dep't of Com. v. New York,</i> 139 S. Ct. 2551 (2019)	10
<i>Dep't of Educ. v. Brown,</i> 600 U.S. 551 (2023)	9
<i>Fam. Rehab., Inc. v. Azar,</i> 886 F.3d 496 (5th Cir. 2018)	2
<i>Funeral Consumers All., Inc. v. Serv. Corp. Int'l,</i> 695 F.3d 330 (5th Cir. 2012)	5, 6
<i>Hancock Cnty. Bd. of Sup'rs v. Ruhr,</i> 487 F. App'x 189 (5th Cir. 2012)	6

<i>Heckler v. Ringer,</i> 466 U.S. 602 (1984)	2
<i>Jaraba v. Blinken,</i> 568 F. Supp. 3d 720 (W.D. Tex. 2021).....	6
<i>Johnson v. HHS,</i> 142 F. App'x 803 (5th Cir. 2005)	5
<i>June Med. Servs. LLC v. Russo,</i> 140 S. Ct. 2103 (2020).....	10
<i>Olim v. Wakinekona,</i> 461 U.S. 238 (1983).....	9
<i>Paterson v. Weinberger,</i> 644 F.2d 521 (5th Cir. 1981).....	6
<i>Physician Hosps. of Am. v. Sebelius,</i> 691 F.3d 649 (5th Cir. 2012).....	2
<i>Shalala v. Ill. Council on Long Term Care, Inc.,</i> 529 U.S. 1 (2000), <i>passim</i>	
<i>Summers v. Earth Island Inst.,</i> 555 U.S. 488 (2009).....	6, 9
<i>Sw. Pharmacy Sols., Inc. v. CMS,</i> 718 F.3d 436 (5th Cir. 2013)	3
<i>Texas v. United States,</i> 809 F.3d 134 (5th Cir. 2015)	8
<i>Town of Castle Rock v. Gonzales,</i> 545 U.S. 748 (2005)	9
<i>TransUnion LLC v. Ramirez,</i> 141 S. Ct. 2190 (2021).....	10
<i>True Health Diagnostics, LLC v. Azar,</i> 392 F. Supp. 3d 656 (E.D. Tex. 2019).....	5
<i>Weinberger v. Salfi,</i> 422 U.S. 749 (1975).....	2, 4

STATUTES

2 U.S.C. §§ 901, <i>et seq.</i>	4
28 U.S.C. § 1406.....	10
42 U.S.C. § 405.....	3
42 U.S.C. § 1320f-1.....	6, 7, 8
42 U.S.C. § 1320f-2.....	7, 8
42 U.S.C. § 1320f-7.....	5
42 U.S.C. § 1395ff.....	2, 3
42 U.S.C. § 1395ii.....	2
42 U.S.C. § 1395w-3	7
42 U.S.C. § 1395w-102	3, 4
42 U.S.C. § 1395w-104	3
42 U.S.C. § 1395w-3a	3, 4, 6

REGULATIONS

42 C.F.R. § 405.990.....	5
--------------------------	---

OTHER AUTHORITIES

Adam Zamecnik, J&J signs Stelara biosimilar settlement deal, Pharm. Tech. (Aug. 8, 2023), https://perma.cc/L64H-9U77.....	8
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INTRODUCTION

Plaintiffs do not dispute that this case should be dismissed for lack of venue unless this Court has subject-matter jurisdiction over the claims of the National Infusion Center Association (NICA)—the only Plaintiff with any relevant connection to the Western District of Texas. But NICA has failed to carry its burden to show subject-matter jurisdiction, for two independent reasons.

First, as for jurisdiction under the Medicare Act, binding precedent “demands the ‘channeling’ of virtually all legal attacks through the agency” first. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). NICA’s claims are no exception. Although this subject is addressed only in cursory fashion at the end of Plaintiffs’ opposition brief, it is independently sufficient to dispose of this case—without the need to even consider standing (much less the merits).

Second, as for Article III standing, NICA scrambles to assert new theories and new facts that do not appear in the complaint. Even if that were procedurally proper, the same basic problem persists: extensive reliance on unsupported speculation about harms NICA’s members *might* suffer “no later than 2028.” Pls.’ Opp’n, ECF No. 47. That is not enough to show Article III injury.

Plaintiffs’ claims would ultimately fail on the merits, in whatever forum they may eventually be considered. *See Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, — F. Supp. 3d. —, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023) (denying preliminary injunction motion in similar case). But there is no occasion to reach the merits here—instead, NICA should be dismissed for lack of subject-matter jurisdiction, and this entire case should then be dismissed for lack of venue.

ARGUMENT

I. Plaintiff NICA should be dismissed for lack of subject-matter jurisdiction.

A. NICA has not satisfied the jurisdictional prerequisites of the Medicare Act.

As Defendants explained in their motion, NICA’s claims are barred by the jurisdictional channeling requirements of the Medicare Act. Plaintiffs’ opposition brief (at 17–19) barely responds to that argument, and what it does say all but confirms that the Court lacks jurisdiction over NICA.

1. As a threshold matter, the Supreme Court, the Fifth Circuit, and this Court have all applied the Medicare Act’s channeling provisions to disputes over Medicare reimbursement. *See, e.g., Ill.*

Council, 529 U.S. at 10; *Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 440 (5th Cir. 2013); *Am. Med. Hospice Care, LLC v. Azar*, No. 5:20-cv-757-DAE, 2020 WL 9814144, at *3–4 (W.D. Tex. Dec. 9, 2020) (Ezra, J.). So to the extent that Plaintiffs suggest that these principles apply “only with respect to appeals from an ‘initial determination [of social security benefits] under subsection (a)(1)’” of the Social Security Act, Opp’n at 17 (quoting 42 U.S.C. § 1395ff(b)(1))—rather than “to reimbursement decisions under Medicare” more generally, *id.*—that theory is foreclosed by precedent.¹

Plaintiffs likewise imply that it matters that their “claims are *constitutional challenges*” and that (in their view) NICA’s “standing is grounded in *constitutional* harm from the operation of the IRA.” Opp’n at 18–19 (emphases altered). But “[t]he Supreme Court has also explicitly rejected the argument that constitutional challenges are free from Section 405(h)’s requirements.” *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 656 (5th Cir. 2012) (citing *Weinberger v. Salfi*, 422 U.S. 749, 762 (1975); *Heckler v. Ringer*, 466 U.S. 602, 615–16 (1984)). As this Court has explained, the question of whether NICA will be “deprived of a fundamental liberty or property interest” or suffer other constitutional harm relating to Medicare reimbursements “is undoubtedly an issue arising under the Medicare Act” for channeling purposes. *Am. Med. Hospice Care*, 2020 WL 9814144, at *4. And these “provider[s]” participation in the Medicare Program in turn provides the sole basis for [NICA’s] standing to bring its procedural due process [and other constitutional] claim[s]—without its claim for benefits, [a NICA member] would not be in a position to assert that it is entitled to any sort of . . . hearing” or other constitutional relief. *Id.* So the fact that NICA brings constitutional claims does not solve its channeling problem.

2. Attempting to overcome this precedent, Plaintiffs (at 17–18) question the applicability of section 1395ff on the ground that they are not challenging an agency determination. That argument proves the government’s point. Section 1395ff is the only relevant avenue for judicial review of Medicare reimbursement claims. *See* 42 U.S.C. § 1395ii (stripping general federal-question jurisdiction,

¹ Plaintiffs similarly quote statutory language about “the Commissioner of Social Security,” Opp’n at 17, seemingly implying a mismatch with this suit against HHS. But the statute provides that “any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services.” 42 U.S.C. § 1395ii; *see also, e.g.*, *Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 500 n.4 (5th Cir. 2018).

via incorporation by reference to 42 U.S.C. § 405). Plaintiffs are correct that section 1395ff provides for judicial review “*only* with respect to appeals from an ‘initial determination [of benefits]’” by the agency, Opp’n at 17 (quoting 42 U.S.C. § 1395ff(b)(1)) (emphasis by Plaintiffs), with which a provider is “dissatisfied,” 42 U.S.C. § 1395ff(b)(1)(A). They are also correct that there has not yet been any “initial determination” of their Medicare reimbursement by the agency here, *see* Opp’n at 17—after all, the price changes that NICA is concerned about will not take affect for many years. That is precisely why this Court lacks subject-matter jurisdiction over NICA and its members. If the absence of an agency decision were enough to avoid channeling, there would be no channeling doctrine at all.²

3. Plaintiffs also argue that the Negotiation Program “was not established under subchapter XVIII, but rather in subchapter XI” of Title 42, so it is not covered by section 1395ii’s reference to “this subchapter.” Opp’n at 18. But that premise is incorrect (or at least materially incomplete). To be sure, *some* provisions of the Negotiation Program appear in subchapter XI, but others—including many that are core to Plaintiffs’ claims—appear in subchapter XVIII. Through this lawsuit, NICA is seeking to ensure that Medicare pays its members using the formula in the pre-IRA version of 42 U.S.C. § 1395w-3a(b)(1)(B), instead of the (allegedly unconstitutional) post-IRA version, as amended by IRA section 11001(b)(1). *See* Compl. ¶ 21 (describing these statutory changes, though tellingly without any citation). That provision is in subchapter XVIII, and thus covered by section 1395ii—even on NICA’s interpretation (as well as the District of Maryland’s, in the only case that Plaintiffs cite, at 18).³

² Plaintiffs cite nothing to the contrary, other than (at 17–18) a partial and unexplained quotation from one footnote in *D&G Holdings, LLC v. Becerra*, 22 F.4th 470 (5th Cir. 2022). That case is inapposite—among other reasons, the key question there was whether the agency’s “effectuation[]” of a prior administrative decision was sufficiently connected “with the initial exhausted agency action” to consider channeling requirements satisfied. *Id.* at 476–77. In other words, the plaintiff in that case *had* gone through the administrative process and obtained an “initial, properly exhausted, administrative decision” before suing in federal court. *Id.* at 472. NICA has not. That distinction is dispositive.

³ Plaintiffs now also purport to recast their claims (in part) as a challenge to IRA section 11001(b)(1)’s amendment to 42 U.S.C. § 1395w-102, which limits Part D plan payments to pharmacies. *See* Opp’n at 1–3, 14. That provision is also found in subchapter XVIII, as is the provision governing Part D administrative claims, 42 U.S.C. § 1395w-104(g), (h); *see Sw. Pharmacy Sols.*, 718 F.3d at 444–45.

In any event, Plaintiffs' argument is beside the point. As the Fifth Circuit (and this Court) have recognized, claims necessarily "arise under the Medicare Act when they are 'inextricably intertwined' with the underlying substantive claim for benefits" that *does* arise under the Medicare Act. *Am. Med. Hospice Care*, 2020 WL 9814144, at *4; *accord Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 286 (5th Cir. 1999). That standard is satisfied here. *See, e.g.*, Compl. ¶¶ 4, 15, 20–21, 39, 66, 68, 106, 117, 144 (referencing providers' Part B reimbursements, which are governed by an IRA provision amending subchapter XVIII, 42 U.S.C. § 1395w-3a(b)(1)(B)). Plaintiffs' opposition brief dispels any doubt—it is peppered with material citations to subchapter XVIII. *See* Opp'n at 4, 14, 15 (citing 42 U.S.C §§ 1395w-3a, 1395w-102).

NICA protests that the government "cites no case like this one—a facial constitutional challenge to a statute in a different subchapter—where Section 405 channeling was found to apply." Opp'n at 17. Not so. The D.C. Circuit held in *Community Oncology Alliance, Inc. v. OMB*, 987 F.3d 1137 (D.C. Cir. 2021) (cited in Defs.' Mot. to Dismiss at 13, ECF No. 39 ("MTD")), that there was no jurisdiction over a constitutional challenge to an order issued under an entirely different statute. There, as here, the plaintiff argued that statutory provisions outside of subchapter XVIII—in that case, the Balanced Budget Act, 2 U.S.C. §§ 901 *et seq.*—unconstitutionally reduced Medicare Part B drug reimbursements under 42 U.S.C. § 1395w-3a. The D.C. Circuit held that the claims were channeled, as dictated by Supreme Court precedent: "To contend that such an action does not arise under the Act whose benefits are sought is to ignore both the language and the substance of the complaint." *Cmty. Oncology*, 987 F.3d at 1143 (quoting *Salfi*, 422 U.S. at 761). In other words, "even if [the plaintiff's] claims could be described as arising under the Constitution or the Balanced Budget Act, all that matters under section 405(h) is that the claims *also* arise under the Medicare Act." *Id.* (emphasis added). So too here. *Compare* Opp'n at 4, 14, 15 (citing 42 U.S.C § 1395w-3a, in subchapter XVIII), *with id.* at 19 n.3 (purporting to distinguish *Community Oncology*, yet *also* citing 42 U.S.C § 1395w-3a).

In *Association of Community Cancer Centers v. Azar*, 509 F. Supp. 3d 482 (D. Md. 2020), on which Plaintiffs rely, a district court in Maryland also found it significant that the plaintiff "did 'not make any specific or individual claims for reimbursement under subchapter XVIII.'" Opp'n at 18 (quoting 509

F. Supp. 3d at 491). The Fifth Circuit, however, has taken a different approach: that NICA’s members “do[] not *directly* seek Medicare benefits does not bar application of § 405.” *Johnson v. HHS*, 142 F. App’x 803, 804 (5th Cir. 2005) (emphasis added) (citing *Ill. Council*, 529 U.S. at 15). For purposes of Medicare Act channeling, “[t]he term ‘arising under’ is broadly construed to encompass all claims for relief, regardless of whether the claimant seeks benefits, or declaratory or injunctive relief.” *True Health Diagnostics, LLC v. Azar*, 392 F. Supp. 3d 656, 662 (E.D. Tex. 2019); *see Ill. Council*, 529 U.S. at 13–14. So the absence of a direct request for benefits in the prayer for relief is irrelevant.

4. Finally, Plaintiffs argue that “channeling does not apply” because of 42 U.S.C. § 1320f-7, Opp’n at 19, which precludes review of some IRA implementation decisions. Yet again, the Supreme Court has held otherwise: “[t]he fact that the agency might not provide a hearing for that particular contention,” or even “may lack the power to provide one, . . . is beside the point” for purposes of Medicare Act channeling. *Ill. Council*, 529 U.S. at 23. To that end, both the Medicare Act and CMS regulations offer expedited review of constitutional claims. *See* 42 U.S.C. § 1395ff(b)(1)(F)(2); 42 C.F.R. § 405.990(c)(2). As Defendants have acknowledged, if these claims are “rejected during the administrative process,” NICA or its members “could then sue in federal court, where [their] constitutional arguments for greater reimbursement would be adjudicated.” MTD at 15. But the requirement to first present that argument to the agency is unaffected by section 1320f-7.

B. NICA has not identified any member with Article III standing.

As for Article III standing, in response to Defendants’ facial attack on the sufficiency of the complaint, Plaintiffs point to a range of alleged injuries—few of which are actually alleged in the complaint and none of which would be sufficient to establish standing in any event.

1. As an initial matter, Plaintiffs do not dispute that their complaint fails to allege any injury to identified NICA members. Opp’n at 16. They instead contend that this argument is “moot” because they have now named a member in their brief, and they assert that they need not do so at the pleading stage. But the Fifth Circuit has been unequivocal that “[a]n organization lacks standing if it fails to adequately ‘allege that there is a threat of injury to any individual member of the association’ and thus ‘fails to identify even one individual’ member with standing.” *Funeral Consumers All., Inc. v.*

Serv. Corp. Int'l, 695 F.3d 330, 344 (5th Cir. 2012) (brackets and quotation marks omitted).⁴ The required allegations as to individual members are not properly raised in opposition to the motion to dismiss. *See, e.g., Jaraba v. Blinken*, 568 F. Supp. 3d 720, 727 (W.D. Tex. 2021); *see also, e.g., Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. 1981). Plaintiffs' standing arguments fail for this reason alone.

2. Even crediting their new assertions outside of the complaint, Plaintiffs still have not established any actual or imminent injury to any of NICA's members—identified or otherwise.

As to Plaintiffs' feared economic injuries, the complaint includes allegations only about NICA members' operation of “outpatient facilities [that] administer [infusion drug] treatments,” which are services covered under Medicare Part B. Compl. ¶ 21. And those generic allegations—that NICA “expects” its unidentified members' reimbursements under Part B to decrease, eventually leading to lower overall revenues, *id.*—are far too vague and speculative to support Article III standing. In their attempt to solve this problem, NICA has now identified a member, BioTek, and named an infusion drug, Stelara, which was selected for negotiation for initial price applicability year 2026 with respect to its coverage under Part D, *see* 42 U.S.C. § 1320f-1(a), (d)(1). This attempt falls short—even ignoring the threshold problem that the complaint remains facially insufficient.

Plaintiffs assert that BioTek's Part B reimbursements have “historically” been “based on the average sales price (ASP) . . . plus 6%.” Supp. Nyquist Decl. ¶ 8, ECF No. 47-2. And they argue that future reimbursement for selected drugs under Part B—negotiated prices plus 6%, 42 U.S.C. § 1395w-3a(b)(1)(B)—will decrease when negotiated prices take effect in 2028 or later. Opp'n at 15. But Plaintiffs ignore that some providers are likely to save money on their drug-acquisition costs for any

⁴ Plaintiffs cite two non-precedential cases suggesting that organizations representing large groups of individual voters need not always name names to “adequately allege[] that some of its members” faced Article III injury. *Hancock Cnty. Bd. of Sup'r's v. Ruhr*, 487 F. App'x 189, 198 (5th Cir. 2012); *see Am. C.R. Union v. Martinez-Rivera*, 166 F. Supp. 3d 779, 804 (W.D. Tex. 2015); Opp'n at 16–17. Neither of those cases cite the relevant Fifth Circuit precedent, and *Hancock* was issued just two weeks before *Funeral Consumers Alliance* reaffirmed (at the pleading stage) the relevant requirements under *Summers*—in which the Supreme Court “rejected the contention that standing can be established by ‘accepting the organization’s self-description of the activities of its members,’” 695 F.3d at 344 (quoting 555 U.S. at 497), and also explicitly discussed the “requirement of *naming* the affected members,” 555 U.S. at 499 (emphasis added).

selected drug under Part B, because they will (for the first time) be guaranteed an opportunity to purchase them at negotiated prices. *See* 42 U.S.C. § 1320f-2(a)(3). So even if *reimbursements* fall, providers' *profits* on sales of these drugs may increase—in particular, for providers who currently acquire drugs at above-average prices (as, presumably, roughly half of them do). *See* MTD at 11. Plaintiffs still make no allegations regarding BioTek's acquisition costs of any drug. So any theory of financial harm to BioTek still relies on speculation and several variables that are unaccounted for in Plaintiffs' filings.⁵

Nonetheless, Plaintiffs speculate that NICA members' reimbursements under Medicare Part B will *eventually* decrease for the administration of infusion drugs such as Stelara. Opp'n at 13–14. But Plaintiffs concede that even if Stelara remains a selected drug, no negotiated prices will take effect with respect to Part B until 2028. *See id.*; 42 U.S.C. § 1320f-1(a), (d)(1). They maintain that this time lag is insignificant because an infusion drug covered under Part B “*will*” eventually be selected for negotiation. Opp'n at 12. But that hypothetical drug's future *selection* is not an injury in itself—rather, any injury to NICA members would result from a (currently hypothetical) revenue decrease, a possibility that is affected by several uncertain variables that Plaintiffs ignore, as discussed above. And the massive lag time only heightens the speculative nature of Plaintiffs' theory of economic injury. *Cf. Attala Cnty., Miss. Branch of NAACP v. Evans*, 37 F.4th 1038, 1043 (5th Cir. 2022) (a plaintiff must show a “real and immediate threat,” and “immediacy does imply a short timeframe”).

To that end, Plaintiffs do not dispute that in the years before any negotiated price goes into effect for a drug under Part B, many factors could change current predictions about which drugs may

⁵ Plaintiffs also assert that the negotiated price for Stelara *under Part D* may affect its average sales prices (ASPs) and therefore reimbursements *under Part B*, even before 2028. Opp'n at 14–15. But even ignoring drug-acquisition costs (discussed above), as well as industry predictions that Stelara is deselected in the coming years, *see infra* at 8, Plaintiffs misunderstand how ASPs are calculated, which is critical to this (untimely) theory. An ASP is based on the net price of a drug after rebates and discounts. 42 U.S.C. § 1395w-3(c)(3). So for a negotiated price of a selected drug under Part D to have any effect on the ASP for that drug, the drug manufacturer would need to both agree to a price that is lower than the current net price of the drug (after discounts) and avoid offsetting price changes in the private market that also factor into the ASP calculation. None of these events, which depend on independent decision-making by third parties, is “certainly impending.” *Clapper*, 568 U.S. at 409.

be selected. MTD at 10. For example, a generic or biosimilar competitor could enter the market, which would remove a drug from the list of those eligible for price negotiation under mandatory statutory criteria. *See* 42 U.S.C. § 1320f-1(c). Stelara proves this point: according to public reporting (and statements by the manufacturers themselves), the launch of a biosimilar competitor to Stelara is expected no later than early 2025. *See, e.g.*, Adam Zamecnik, *J&J signs Stelara biosimilar settlement deal*, Pharm. Tech. (Aug. 8, 2023), <https://perma.cc/L64H-9U77>. If those predictions are realized, Stelara will be deselected, and negotiated prices will *never* take effect for the administration of Stelara under Part B. *See* 42 U.S.C. § 1320f-1(c). Plaintiffs thus face no “certainly impending” future harm from the selection of Stelara selection for negotiation. *Clapper*, 568 U.S. at 401.

Attempting to overcome these problems, Plaintiffs now state for the first time that NICA’s members are not only medical providers that administer medications under Part B, but they also operate in-house pharmacies that sell medications covered under Part D. *See* Opp’n at 3; Zweben Decl. ¶ 2, ECF No. 47-1. Nowhere in the complaint do Plaintiffs so much as hint at this aspect of NICA members’ business, much less include relevant allegations about how they believe individual members will be harmed. *Contra* Opp’n at 13 (cherry-picking the words “and Part D” from paragraph 21 of the complaint, which states merely that “the Program [will] appl[y] to provider-administered drugs under Medicare Part B and Part D”). In any event, this new theory would also fail, for similar reasons. Plaintiffs continue to ignore that many pharmacies may well ultimately *save* money relative to their current drug-acquisition costs. 42 U.S.C. § 1320f-2(a)(3)(A). And CMS has not yet even determined the Part D reimbursement policy for pharmacies. *See* Revised Guidance at 41–42. Any particular pharmacy may break even or be better off after the challenged statutory changes take effect.

Finally, Plaintiffs suggest counterintuitively that they could have standing—even based on a theory of financial harm—if they were to *profit* from this program, insisting that “standing analysis is not an accounting exercise.” Opp’n at 16 (quoting *Texas v. United States*, 809 F.3d 134, 155 (5th Cir. 2015)). But as *Texas* confirms, when analyzing injury in fact, courts must (at the very least) consider “offsetting benefits that are of the same type and arise from the same transaction as the costs.” 809 F.3d at 155. Those are the exact sorts of benefits that Plaintiffs continue to ignore.

In sum, although it may be difficult to forecast precisely all of the winners and losers from the statute at this early stage, Plaintiffs alone bear the burden of identifying a NICA member that faces an actual or imminent injury—and that injury “must be ‘certainly impending’; mere ‘[a]llegations of possible future injury’ do not suffice.” *Attala Cnty.*, 37 F.4th at 1042 (quoting *Clapper*, 568 U.S. at 409); see *Summers v. Earth Island Inst.*, 555 U.S. 488, 497 (2009). Plaintiffs have not met that burden here.

3. Finally, Plaintiffs argue that NICA’s members face “procedural injuries” due to the mere existence of “an unconstitutional decision-making scheme” that applies to (non-party) drug manufacturers. Opp’n at 6. This argument ignores that “the ‘deprivation of a procedural right without some concrete interest that is affected by the deprivation—a procedural right *in vacuo*—is insufficient to create Article III standing.’” *Dep’t of Educ. v. Brown*, 600 U.S. 551, 562 (2023) (quoting *Summers*, 555 U.S. at 496). So the bottom-line question for standing remains unchanged: that is, whether NICA faces any injury in the form of a “deprivation” of some “concrete interest”—including whether NICA can “satisfy the well-established requirement that threatened injury must be certainly impending.” *Clapper*, 568 U.S. at 401. For the reasons above, NICA cannot—and merely restating that Plaintiffs consider the IRA’s procedures to be unconstitutional does not solve their problem. Otherwise, there would be standing in every constitutional challenge to government procedures.

Plaintiffs fall back on “the ‘special’ nature of procedural injuries.” Opp’n at 7. But again, “[r]egardless of the *redressability* showing [the Supreme Court] ha[s] tolerated in the procedural-rights context, [it] ha[s] never held a litigant who asserts such a right is excused from demonstrating that it has a ‘concrete interest that is affected by the deprivation’ of the claimed right.” *Brown*, 600 U.S. at 562 (quoting *Summers*, 555 U.S. at 496) (emphasis added). Redressability is irrelevant here, as NICA has not alleged any “actual or imminent” Article III injury in the first place. *Clapper*, 568 U.S. at 409.⁶

Plaintiffs’ arguments about the nondelegation doctrine and the Excessive Fines Clause (at 10–11) are even further afield. “Federal courts do not exercise general legal oversight of the Legislative

⁶ Similarly, Plaintiffs’ procedural-injury “argument is at odds with the rule that ‘[p]rocess is not an end in itself.’” *Town of Castle Rock v. Gonzales*, 545 U.S. 748, 771 (2005) (Souter, J., concurring) (quoting *Olim v. Wakinekona*, 461 U.S. 238, 250 (1983)). Instead, “[i]ts constitutional purpose is to protect a substantive interest to which the individual has a legitimate claim of entitlement.” *Id.*

and Executive Branches,” *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021), so whether Plaintiffs believe that the government is violating the law makes no difference to the standing analysis. And even if Congress *had* violated the Constitution in this way, it could only have violated the rights of *drug manufacturers*—who (unlike NICA’s members) would be the ones subject to the allegedly unconstitutional process or the allegedly excessive fines—as Plaintiffs appear to recognize (at 11 n.1).

Plaintiffs nonetheless insist that they “can rely on governmental action aimed at third parties if those ‘third parties . . . react in predictable ways.’” *Id.* (quoting *Dep’t of Com. v. New York*, 139 S. Ct. 2551, 2566 (2019)). But they misread the quoted passage from *Department of Commerce*, which is about causation, not injury-in-fact; those plaintiffs “assert[ed] a number of injuries” to themselves—not to third parties. 139 S. Ct. at 2565. Although “predictable” actions of third parties did not break the chain of causation in that case, “a party cannot ordinarily rest his claim to relief on the legal rights or interests of third parties.” *Juno Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2117 (2020). There is no basis for an exception to that rule here, and NICA makes no argument to the contrary.⁷

II. Upon NICA’s dismissal, this case should be dismissed for lack of venue.

As Defendants have explained, “[o]nce NICA is dismissed from this action, the rest follows as a matter of course.” MTD at 16. Plaintiffs do not dispute that their “only theory of venue depends entirely on NICA’s residence,” nor that “a plaintiff who lacks standing (or is otherwise beyond the subject-matter jurisdiction of the court) cannot create venue where it would not otherwise exist.” *Id.* at 17. Plaintiffs likewise do not dispute that, if venue is improper, “the interest[s] of justice” favor dismissal, rather than transfer, under these circumstances. 28 U.S.C. § 1406(a). Accordingly, because the Court lacks subject-matter jurisdiction over NICA, this case should be dismissed for lack of venue.

CONCLUSION

For these reasons, the Court should dismiss Plaintiff NICA for lack of subject-matter jurisdiction under Rule 12(b)(1), and then dismiss this case for lack of venue under Rule 12(b)(3).

⁷ Separately, Plaintiffs also cite (at 10–11) *Axon Enterprises, Inc. v. FTC*, but the rule announced in that case applies only to certain “extraordinary claims” that are “fundamental, even existential” to the structure of a federal agency. 598 U.S. 175, 180 (2023). None of Plaintiffs’ claims “challenges . . . the structure or very existence of an agency.” *Id.* at 189.

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Respectfully submitted,

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